

### **REMARKS/ARGUMENTS**

Claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29 and 86 remain in this application. Independent claims 1, 29 and 86 are currently amended.

The Examiner has rejected claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29 and 86 under 35 U.S.C 112.

In response, Applicants have amended independent claims 1, 29 and 86 to further clarify that the enhancing agent "excludes water from a cleavage site of said substrate to prevent quenching of said light emission by water molecule induced protonation." Support for this amendment can be found on page 11, lines 10-12.

Applicants have amended independent claim 29 to clarify that the method includes "comparing said measurement to a previously prepared calibration curve correlating a series of light signals with a known quantity of enzyme or bacteria producing each signal in the series." Antecedent basis has also been provided for "the quantity of said enzyme".

Applicants have amended claim 86 to clarify the physical elements of the kit, one of which includes instructions for use of the kit in accordance with the described function of each element.

Applicants believe that the foregoing amendments address the Examiner's clarity concerns with the claims and respectfully request that the rejection under 35 U.S.C 112 be withdrawn.

The Examiner has rejected claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29 and 86 under 35 U.S.C. 103(a) as being unpatentable over Nelis (US 5,961,270). Applicants traverse this rejection and offer the following comments.

Applicants have amended claims 1, 29 and 86 to include the step of "transferring said bacteria from said first filter means to a broth" in order to clarify that the culturing step takes place in suspension. Support for this amendment can be found on page 8, lines 8-9. The claims have further been amended to specify that the water sample being analyzed is a drinking water sample. Support for this amendment can be found throughout the specification, for example at page 8, line 11.

Applicants submit that "in order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art

references must teach or suggest all the claims limitations. The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure." See MPEP § 2142, citing In re Vaeck, 947 F.2d 488, 20 USPQ 2d. 1438 (Fed. Cir. 1991).

Applicants point out that Nelis relies upon the counting of microcolonies, not the measurement of luminescence from a filter means. Nelis is specifically discussed and distinguished in the background section of the instant specification on pages 3 and 4. In addition, it is pointed out on page 5, lines 3-5, that the present invention seeks to overcome the disadvantages of prior art assays, in particular the need to count microcolonies.

In the present invention, the bacteria are transferred from the first filter means to a liquid broth and cultured in suspension, then separated from the broth using a second filter means. The advantage pointed out for culturing in a broth suspension is better growth of stressed cells from drinking water samples. There are no microcolonies present on the second filter means. As evidence, Applicants point out page 12, lines 6-8 of their specification, where it is pointed out that, "To determine the presence or quantity of the target organism, observation of microcolonies is not required, since there are no microcolonies present on the [second] filter"

Since Nelis depends upon microcolony formation, the colonies must be kept on the original filter means and allowed to grow in size thereon so that they can be counted. Nelis cannot be modified to transfer cells from the filter to the broth, as this would preclude microcolony formation on the filter. Even if such a modification were made to Nelis, there could be no success in counting any colonies on the second filter means. Applicants therefore submit that any motivation to modify Nelis to include these two aspects of the claimed method could only be attributed to a person skilled in the art through impermissible hindsight analysis (see MPEP § 2142).

Furthermore, the present invention provides surprising evidence of the superior efficacy of the claimed method over conventional colony counting techniques. In Example 5, real drinking water samples (not laboratory generated water samples) containing background bacteria that sometimes inhibit the growth of target bacteria on the commonly used mEndo media, were analyzed using both the present invention and conventional colony counting techniques. With reference to the first line in Table 1, the present invention provided a positive result from a well water sample where the colony counting technique produced a negative result. This evidence of the surprisingly superior efficacy of the claimed method over conventional colony counting techniques could not have been predicted in advance and supports a finding of non-obviousness.

In summary, Applicants respectfully submit that the Examiner has failed to satisfy any of the three basic criteria needed to establish a *prima facie* case of obviousness. Nelis' emphasis on the importance of microcolony formation on the filter teaches away from transferring bacteria from the filter to the broth and, as a result, there is no need or motivation to use a second filter means. Even if these modifications were made to Nelis, there would be no expectation of success due to the absence of microcolonies on the second filter means. At least two claim limitations are therefore not taught or suggested by Nelis. Finally, Applicants have provided evidence of surprisingly superior efficacy over conventional methods, particularly with real drinking water samples. Applicants therefore respectfully request that the rejection under 35 U.S.C 103 (b) be withdrawn.

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In view of the above amendment and remarks, reconsideration on all claims is respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
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